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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/736,428 | 12/15/2003 | Alfred J. Moo-Young | CBR 3.0-017 CONT | 3967 |

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| EXAMINER | |
|---|---|
| WELLS, LAUREN Q | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1617 | |

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/736,428 | MOO-YOUNG ET AL. | |
| | Examiner | Art Unit | |
| | Lauren Q Wells | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 12-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/15/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-22 are pending. Claim 11 is withdrawn from consideration, as it is directed to non-elected subject matter.

### *Election/Restrictions*

This application contains claims directed to the following patentably distinct species of the claimed invention:

a. An ointment, cream and lotion,

b. A gel

c. A powder

d. A spray

e. A transdermal patch

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-6, 14, 16-20, 22 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Arnold Krumholz on 7/1/04 a provisional election was made with traverse to prosecute the invention of "a transdermal patch". The Examiner broadened the search to include sprays, gels, ointments, creams, and lotions, claims 1-10, 12-22. Affirmation of this election must be made by applicant in replying to this Office action. Claim 11 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 12, 14-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Herschler (4,177,267) in combination with Bardin et al. (5,342,834).

The instant invention is directed toward a composition comprising a non-5alpha-reducible, 7alpha-modified androgen in a therapeutically effective amount, being dispersed within a carrier, whereby the flux of the composition is greater than that of testosterone in a similar formulation, , wherein the composition is sufficient to deliver between about 400 to about 1600 micrograms of androgen in bioavailable form over a 24 hour period.

Herschler teaches that androgens such as modified 19-nortestosterone and modified testosterone (col. 10, line 55-col. 11, line19) can be delivered topically in gels (col. 6, lines 61-63). For the amount of androgen, see example 11 at column 11, which teaches 1-10% or 10-100 gm of 17 alpha ethyl-19-nortestosterone. Topical administration is equivalent to transdermal administration. For sprays, lotions, ointments, creams, and gels, see Col. 6, lines 61-63. The reference does not explicitly teach non-5alpha-reducible androgens, a dosage amount of between about 400 to about 1600 micrograms of androgen over a 24 hour period or the flux rate.

Bardin et al. teaches transdermal administration of 7 alpha-methyl-19-nortestosterone. For other non-5alpha-reducible androgens, see col. 2, lines 32-56. The reference suggests various routes of administration and therapeutic amounts at col. 3, lines 64-col. 4, line 9.

The limitations of claim 16 regarding flux and dosage do not provide any quantitative limitations to the claims. The compositions of Herschler contain concentrations of the androgens that are encompassed by the instantly claimed concentrations and, therefore, would be expected

to provide the instantly claimed dosage amounts. It is within the skill in the art to select optimal parameters in a composition in order to achieve a beneficial effect. In re Boesch, 205 USPQ 215 (CCPA 1988). Absent evidence of unexpected results, the concentration and dosage amounts instantly claimed are not considered critical to the invention. Furthermore, the instant invention defines an effective amount of the androgen as 1-80% of the composition, and Herschler teaches androgens in this amount.

The purpose of Herschler is to enhance tissue penetration of the steroids. It is the Examiner's position that enhancement of tissue penetration is equivalent to increased flux rate as instantly claimed. The expression "comprising" permits the presence of other ingredients and does not preclude the presence of other ingredients, active or inactive, even in major amounts. See Moleculon Research Corporation v CBS, Inc. 229 USPQ 805, In re Baxter 210 USPQ 795, 803. The instant claims do not exclude DMSO as disclosed by Herschler. Absent evidence of unexpected results, the flux rate is not given patentable weight over the prior art composition that teaches enhanced tissue penetration.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use 7alpha-methyl-19-nortestosterone, as taught by Bardin et al., in the dosage forms as taught by Herschler because of the expectation of providing transdermal administration of an androgen supplement that does not stimulate abnormal prostate growth (beneficial property of 7alpha-methyl-19-nortestosterone, as taught by Bardin et al.).

Claim 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Herschler and Bardin et al. as applied to claims 1-10, 12, 14-22 above, and further in view of Kwiatek et al. (4,573,996).

Herschler and Bardin et al. are applied as discussed above. The references lack a transdermal patch.

Kwiatek et al. teach transdermal patches as devices for the administration of an active agent to the skin or mucosa. Transdermal patches are taught as preferred formulations for topical application of active ingredients, wherein transdermal patches provide administration of an active ingredient over a period of time, thereby increasing the length of therapeutic effect. See abstract, Col. 1-Col. 2,line 2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the topical compositions of the combined references in the form of a transdermal patch because of the expectation of achieving controlled release of the active ingredient and increased length of therapeutic effect.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is 571-272-0634. The examiner can normally be reached on M&R (5:30-4).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lqw

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER